

FOR PTD-1390
(REV 12-29-99)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

T2328-906561

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/601106

INTERNATIONAL APPLICATION NO.
PCT/GB99/00288INTERNATIONAL FILING DATE
28 January 1999PRIORITY DATE CLAIMED
30 January 1998TITLE OF INVENTION
PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTIONAPPLICANT(S) FOR DO/EO/US
Colin Anthony KEMP

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
 1. Correspondence Address and Notice of Filing Without Declaration
 2. Verified Statement Claiming Small Entity: Independent Inventor and Small Business Concern
 3. Claim for Priority
 4. Information Disclosure Statement, w/PTO form 1449
 5. International Search Report
 6. International Preliminary Examination Report
 7. English Translation of Application (Spec. 6 pgs; 13 claims (2 pgs.); Abstract
 8. Check for \$849.00
 9. Corres. Address & Notice of Filing without Declaration

U.S. APPLICATION NO. (if known, see 37 CFR 1.51) 09/601106		INTERNATIONAL APPLICATION NO. PCT/GB99/00288		ATTORNEY'S DOCKET NUMBER T2328-906561	
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17. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) : Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$970.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$840.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$670.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) \$96.00 <div style="text-align: right;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div>				CALCULATIONS PTO USE ONLY	
				<div style="border: 1px solid black; height: 150px; width: 100%;"></div>	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input checked="" type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 485.00	
				\$ 65.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	13 - 20 =	0	X \$18.00	\$ 0	
Independent claims	4 - 3 =	1	X \$78.00	\$ 39.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$260.00	\$ 130.00	
TOTAL OF ABOVE CALCULATIONS =				\$ 719.00	
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	
SUBTOTAL =				\$ 719.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ 130.00	
TOTAL NATIONAL FEE =				\$ 849.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 849.00	
				Amount to be refunded: \$	
				charged: \$	

a. ☒ A check in the amount of \$ 849.00 to cover the above fees is enclosed.

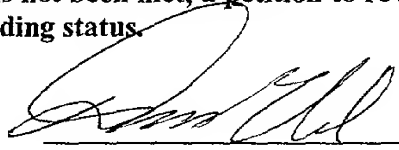
b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
 A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
 overpayment to Deposit Account No. 50-1165. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Dennis P. Clarke
 Miles & Stockbridge
 1751 Pinnacle Drive, Suite 500
 McLean, VA 22102-3833
 Telephone (703) 903-9000
 Facsimile (703) 610-8686


 SIGNATURE:
 Dennis P. Clarke
 NAME
 22,549
 REGISTRATION NUMBER

PATENT

Attorney's Docket No:

Applicant or Patentee:

Serial or Patent No:

Filed or Issued:

For:

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(b)) -- INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled:

PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION

described in

- ☒ The specification filed herewith.
- ☐ Application Serial No. _____, filed _____.
- ☐ Patent No. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☐ No such person, concern, or organization
- ☒ Persons, concerns or organizations listed below*

***NOTE:** Separate verified statements are required from each named person, concern or organization having rights to the invention overriding to their status as small entities. (37 CFR 1.27).

FULL NAME: FUTURA MEDICAL LIMITED

ADDRESS: Antrobus House, 18 College Street, Peterstield, Hampshire GU13 4AD, UK

☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME: _____
ADDRESS: _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME: _____
ADDRESS: _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.



Signature of Inventor

Date: 25 July 2000

Signature of Inventor

Date: _____

Signature of Inventor

Date: _____

09601105-091500

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Filed: Concurrently Herewith

For:

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.2 (d) AND 1.27 (e)) - SMALL BUSINESS CONCERN**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below;
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: FUTURA MEDICAL LIMITED

ADDRESS OF CONCERN: Antrobus House, 18 College Street, Petersfield,
Hampshire GU13 4AD UK

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41 (a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above, with regard to the invention entitled " * " by inventor(s) KEMP, C. A. described in

- *PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION
☒ the specification filed herewith
☐ Application No. _____, filed _____
☐ patent No. _____, issued _____

The rights held by the above identified small business concern are exclusive.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: KEMP, Colin, Anthony

TITLE OF PERSON OTHER THAN OWNER: Managing Director

ADDRESS OF PERSON SIGNING: 18A Beechworth Road, Havant, Hampshire PO9 1AX, UK

DATE: 26.7.2000 SIGNATURE _____

PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION

This invention relates to a preparation for topical application to the male sexual organ, especially for the treatment of erectile dysfunction.

Erectile dysfunction is a widespread problem with human males, albeit not commonly discussed in public. It is not regarded as a medical condition susceptible to treatment in the conventional sense being to a large extent caused by a mental condition or at least exacerbated by a loss of confidence following an initial experience caused perhaps by tiredness or an over-indulgence in food or alcohol. Nevertheless, the consequences are serious to the sufferer, resulting in psychological damage and in many cases frustrating the normal fertilisation processes so that artificial insemination procedures must be used if procreation is required. Procedures for overcoming this problem have been proposed which can involve the surgical implantation of stiffening devices as described in GB-A-1476804, US-A-5242391 and other patents. Chemotherapeutical approaches have been proposed which require the injection of vasodilator compositions immediately prior to intercourse. The injection takes place on or near the penile shaft. Neither procedure is attractive and both approaches can result in revulsion or distress on the part of the partners involved. US-A-5059603 and US-A-4801587 propose topical application of compositions containing vasodilators. US-A-5059603 proposes the use of a composition including a combination of a vasodilator and vasoconstrictor in a carrier intended to assist absorption of the active

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ingredients through the skin of the penis, the active ingredients being chosen so that the vasodilator acts more quickly than the vasoconstrictor whereby an erection of the penis, having been initiated by the action of the vasodilator, is sustained by the action of the vasoconstrictor. Vasodilators said to be appropriate for use in such compositions include nitroglycerin, papaverine, hydralazine, sodium nitroprusside and phenoxybenzamine, among others. Vasoconstrictors include caffeine, 3-(2-aminoethyl)indole derivatives and adrenaline. US-A-4801587 proposes a composition in the form of an ointment and including a vasodilator selected from papaverine, hydralazine, sodium nitroprusside, phenoxybenzamine and phentolamine mixed in a base with dimethylsulfoxide as a skin-absorption agent. Dimethylsulfoxide is also proposed for the same purpose in US-A-5059603.

It has now been found that nitroglycerin (glyceryl trinitrate) can be used as a vasodilator in a composition for topical application to the penis in conjunction with carrier materials without either a vasoconstrictor or dimethyl sulfoxide, which is known to be a toxic material, and that such compositions are effective for the treatment of erectile dysfunction.

According to one aspect of the present invention, there is provided the use of a combination of compounds in the preparation of a composition for the treatment of erectile dysfunction in human males, the compounds comprising glyceryl trinitrate and lanolin.

According to another aspect of the invention, a method of treatment of erectile dysfunction in males comprises applying to the penis a composition comprising an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin of the penile shaft.

The carrying out of the method of the invention before sexual intercourse results in an erection of the penis which not only enables subsequent intercourse to take place but also provides for the subject male a mental state of renewed confidence in his ability as a sexual partner and may provide for the other partner a sense of relief from any self-doubt concerning her abilities to stimulate her partner to a state of sexual arousal. The method according to the invention is thus a means of acquisition of a particular state of mental well-being or a method of enhancing or promoting sexual appeal or sexual confidence, with cosmetic overtones in terms of enhancing the appearance of the male anatomy in the circumstances of intimate sexual activity.

The invention also includes, in a further aspect, the use of glyceryl trinitrate and lanolin in the treatment of erectile dysfunction in human males.

The glyceryl trinitrate acts as a vasodilator according to its established utility for example in the treatment of angina pectoris but it has not hitherto been recognised that

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in simple combination with lanolin there could be provided an effective treatment of erectile dysfunction in human males.

Glyceryl trinitrate is a material which is per se explosive. For use in the present invention, it is preferably adsorbed on a solid stabilizer in finely-divided particulate form, the particles being in the sub-micron size range to render them capable of passage through the skin. A preferred stabilizer compound is lactose on which the glyceryl trinitrate may be adsorbed at a concentration of from 5 to 20% by weight, for example 10% by weight. Glyceryl trinitrate is preferably present in a concentration up to 5% by weight of the overall formulation; a concentration of 1% or 2% by weight is generally sufficient to be effective.

The lanolin acts as a lubricant or moisturiser and also enhances skin absorption. It is known to be non-toxic and for the purpose of the present invention should be used as a medical grade such as "Medilan" (Trade Mark).

Preferably, compositions according to the invention also include a physical stabilizer such as a paraffin cream; optionally, the compositions contain other ingredients such as fragrances and/or colorants. The paraffin cream, for example provided as White Soft Paraffin B.P., promotes stability of the composition on the skin and also acts as a water-repellant barrier and lubricant.

The composition also includes water to adjust the overall viscosity or consistency and concentration of the active ingredient to the desired levels, bearing in mind that for ease of use the composition should be in the form of a physically-stable suspension of the active ingredient in a creamy emulsion which is sufficiently low in viscosity to be readily applied to and spread over the skin of the penis at ordinary body temperatures.

An example of a composition for use according to the present invention is given below:

<u>Ingredient</u>	<u>Weight %</u>
Glyceryl trinitrate (10% in lactose)	10
Lanolin ("Medilan")	44
White Soft Paraffin B.P.	21
Demineralized Water	25

In use, two grams of the above formulation, which has the form of a white cream, was applied to the glans penis and penile shaft and gently massaged into the skin. The effect was to produce an erection of the penis which was sustained for approximately 45 minutes. The effect in producing an erection may be enhanced by other stimuli of tactile, audio and/or visual nature.

The formulation may be used in conjunction with a condom, in which the formulation is applied to the penis and a condom applied in the usual manner after an erection has been attained. Condoms suitable for use with the formulation are preferably of the non-latex type, for example formed from polyurethane.

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CLAIMS:

1. Use of a combination of compounds in the preparation of a composition of for the treatment of erectile dysfunction in human males, the compounds comprising glyceryl trinitrate and lanolin.
2. A method of cosmetic treatment for improving the bodily appearance of human males, the method comprising applying to the penis a composition comprising an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin.
3. A method of treatment of erectile dysfunction in males comprises applying to the penis a composition comprises an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin of the penile shaft.
4. The use of glyceryl trinitrate and lanolin in combination as a cosmetic product.
5. The use as claimed in claim 1 or claim 4, or a method of cosmetic treatment as claimed in claim 2 or claim 3, in which the glyceryl trinitrate is adsorbed on a solid stabilizer in finely-divided particulate form.

7. The use or the method according to claim 6, in which the glyceryl trinitrate is adsorbed on the lactose at a concentration of from 5 to 20% by weight.
8. The use or the method according to any preceding claim, in which the glyceryl trinitrate is present in a concentration up to 5% by weight.
9. The use or the method according to any preceding claim, in which the composition also includes a physical stabilizer.
10. The use or the method according to claim 9, in which the composition also includes water.
11. The use or the method according to any preceding claim, in which the composition consists essentially of 10wt% glyceryl trinitrate (10% in lactose), 44wt% lanolin, 21wt% white soft paraffin B.P. and 25wt% demineralized water.
12. The use of a composition as claimed in claim 1 in conjunction with a condom.
13. In combination, a composition as defined in claim 1 and a condom.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

ATTORNEY'S SOCIETY NUMBER
T2328-906561

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought of the invention entitled:

PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION

one specification of which (check only one item below):

- ☐ is attached hereto.
☒ was filed as United States application

Serial No. 09/601,106

on July 27, 2000

and was amended

on _____ (if applicable).

- ☒ was filed as PCT international application

Number: PCT/US99/00288

on 28 January 1999

and was amended under PCT Article 19

on _____ (if applicable).



I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim priority benefit under Title 35, United States Code, §119 of the following United States Provisional Application and of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

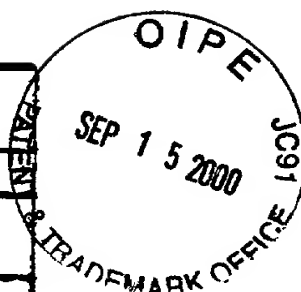
PRIOR U.S. PROVISIONAL AND FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (If PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMS (Under 35 U.S.C. 119)
UNITED KINGDOM	9802078.7	30 JANUARY 1998	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

Combined Declaration for Patent Application and Power of Attorney (Continued)
(Includes Declaration to PCT International Applications)

ATTORNEY'S POWER OF ATTORNEY

T2328-906561



205	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
206	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
207	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
208	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
209	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
210	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

SIGNATURE OF INVENTOR 205	DATE 15-9-2000	SIGNATURE OF INVENTOR 207	DATE
SIGNATURE OF INVENTOR 206	DATE	SIGNATURE OF INVENTOR 208	DATE
SIGNATURE OF INVENTOR 209	DATE	SIGNATURE OF INVENTOR 210	DATE
SIGNATURE OF INVENTOR 211	DATE	SIGNATURE OF INVENTOR 212	DATE
SIGNATURE OF INVENTOR 213	DATE	SIGNATURE OF INVENTOR 214	DATE

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant : Colin Anthony KEMP

International
Application No.: PCT/GB99/00288

International
Filing Date : 28 January 1999

Serial No. :

For : PREPARATION FOR TREATMENT OF ERECTILE
DYSFUNCTION

Filed :

CORRESPONDENCE ADDRESS AND NOTICE
OF FILING WITHOUT DECLARATION

Hon. Commissioner of Patents & Trademarks
Washington, D.C. 20231

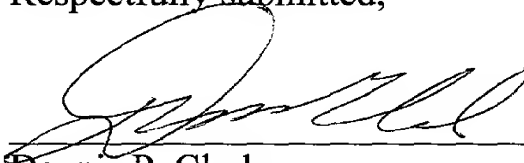
Sir:

This application is being filed on behalf of **Colin Anthony KEMP**, without an executed Declaration. After appropriate notification from the U.S. Patent and Trademark Office, a duly executed Declaration will be submitted:

Please address all communications relative hereto as follows:

Dennis P. Clarke
1751 Pinnacle Drive
Suite 500
McLean, VA 22102
U.S.A.
Tel: (703) 903-9000
Fax: (703) 610-8686

Respectfully submitted,


Dennis P. Clarke
Registration No. 22,549

DPC/maa

Combined Declaration For Patent Application and Power of Attorney (Continued)

(For Use in Connection With PCT International Applications)

ATTORNEY'S POWER OF ATTORNEY

12328-906561

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) originating in the United States of America that were listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	U.S. FILING DATE	FILED	RECEIVED	ABANDONED

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NUMBER ASSIGNED (if any)			
PCT/GB99/00288	28 January 1999			X	

POWER OF ATTORNEY: As a named inventor, I hereby Edward J. Kozdroba (Reg. No. 31,604); Donald P. Chisler (Reg. No. 22,549); William L. Farny (Reg. No. 29,918); John C. Kucias (Reg. No. 32,421); Robert N. Wadsworth (Reg. No. 60,725) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Send Correspondence to: MILES & STOCKBRIDGE
1751 Parkside Drive, Suite 900
McLean, Virginia 22102-3833

Telephone No.
(703) 903-9000

Direct Telephone Calls to:
(703) 610-8572

2	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
2		KING	Colin	Anthony
1	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
1		Hampshire PO9 1AX.	United Kingdom	United Kingdom
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
		18a Seachworth Road Havant	Hampshire PO9 1AX	United Kingdom
2	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
6				
2	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
2	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
3				
3	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY
2	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
4				
4	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	STREET	CITY	STATE & ZIP CODE/COUNTRY

